

Applicants: Saul J. Silverstein et al.  
Serial No.: 09/769,699  
Filed: January 25, 2001  
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**REMARKS**

Claims 1-7, 9, and 11 are pending. Claims 2-4, 9, and 11 have been canceled without prejudice. Claims 1 and 5 has been amended. Support for these amendments may be found in the specification, *inter alia*, at page 10, line 29, page 12, lines 10-11, and page 13, lines 20-24. Applicants submit that these amendments raise no issue of new matter. Thus, claims 1 and 5-7 will be pending and under examination upon entry of this Amendment.

In view of the arguments set forth below, applicants maintain that the Examiner's rejections made in the February 25, 2004 Final Office Action have been overcome, and respectfully request that the Examiner reconsider and withdraw same.

**Rejections Under 35 U.S.C. §112, First Paragraph**

The Examiner rejected claims 1-7, 9, and 11 under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors, at the time the application was filed, had possession of the claimed invention.

In response to the rejection of claims 2-4, 9, and 11, applicants note that these claims have been canceled, rendering the rejection moot.

In response to the rejection of claims 1 and 5-7, applicants respectfully traverse for the reasons of record and for the additional reasons set forth below.

Applicants maintain that the specification adequately describes the claimed invention. Notwithstanding the

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Examiner's assertions to the contrary, it is not necessary to know anything about the three dimensional structure of the 29p protein or which domains of that protein are required for its transporter activity in order to envision the claimed invention. All that is required is that one of skill in the art be able to envision the 29p protein fused at its amino or carboxy terminal end to another polypeptide. Fusion proteins are well-known in the art and the art provides routine methods for the fusion of any two proteins whose primary amino acid sequences are known. The burden is on the Examiner to show by a preponderance of the evidence why a person skilled in the art would not recognize in applicants' disclosure a description of the invention defined by the claims. M.P.E.P. §2163.04. The Examiner has failed to provide any evidence concerning why one of skill would not be able to envision the 29p protein fused to another polypeptide. Therefore, the Examiner has failed to meet the required burden and applicants respectfully request the Examiner to withdraw this rejection.

The Examiner also rejected claims 1-7, 9, and 11 under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to allow one skilled in the relevant art to which it pertains to make and/or use the invention commensurate in scope with the claims.

In response to the rejection of claims 2-4, 9, and 11, applicants again note that these claims have been canceled, rendering the rejection moot.

In response to the rejection of claims 1 and 5-7, applicants respectfully traverse for the reasons of record and for the additional reasons set forth below.

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The Examiner's rejection is based in large part upon the lack of a specific working example of a 29p fusion protein in the specification. However, applicants point out that they need not have actually reduced the invention to practice prior to filing for the claimed invention to be enabled. M.P.E.P. §2164.02. Applicants maintain that given the teachings in the specification and the high level of knowledge and skill in the art regarding making and using fusion proteins, such an example is not necessary for enablement.

The Examiner also based his rejection on the assertion that the field of the present invention is complex and unpredictable. However, the Examiner has provided no evidence to explain why the task of making and using the claimed 29p fusion proteins is complex or unpredictable. Applicants maintain that it is not, namely that one of skill can make the instant fusion proteins (which merely involve N- or C-terminal joining) using routine skill. Likewise, the contacting of a mammalian cell with the instant proteins involves nothing more than routine skill.

In view of the above remarks, applicants maintain that claims 1 and 5-7 satisfy the requirements of U.S.C. §112, first paragraph.

**Rejection Under 35 U.S.C. §112, Second Paragraph**

The Examiner rejected claims 1-7, 9, and 11 under 35 U.S.C. §112, second paragraph, as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention.

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In response to the rejection of claims 2-4, 9, and 11, applicants again note that these claims have been canceled, rendering the rejection moot.

In response to the rejection of claims 1 and 5-7, applicants respectfully traverse for the reasons of record and for the additional reasons set forth below.

The Examiner maintains that the skilled artisan cannot know whether or not a particular variant of the 29p protein is a "naturally occurring variant" falling within the scope of the claims (see page 9, lines 16-18 of the specification). In order to further the prosecution of the instant application, and without conceding the correctness of the Examiner's position, applicants have inserted a Sequence Identifier into claims 1 and 5.

In view of the above remarks, applicants maintain that claims 1 and 5-7 satisfy the requirements of U.S.C. §112, second paragraph.

#### **Summary**

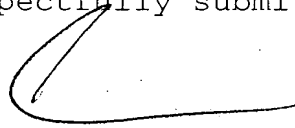
In view of the amendments and remarks made herein, applicants maintain that the claims pending in this application are in condition for allowance. Accordingly, allowance is respectfully requested.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorneys invite the Examiner to telephone them at the number provided below.

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No fee is deemed necessary in connection with the filing of this Amendment. However, if any fee is required, authorization is hereby given to charge the amount of such fee to Deposit Account No. 03-3125.

Respectfully submitted,



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